

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, the specification has been amended to correct minor clerical and typographical errors and the claims have been amended as discussed below. No new matter has been added.

Claims 14, 19-21, 25 and 26 are pending in the application, with 14 being the sole independent claim. Claims 1-13, 15-18, 22-24, and 27-96 have been canceled without prejudice to or disclaimer of the subject matter therein. Independent claim 14 has been amended to delete "greater than about 91% of" from the second clause, and by adding to the previous language in the final clause that the doubling rate is maintained "...after 30 cell doublings". Support for amended claim 14 can be found in the specification as originally filed, for example, at page 29, lines 25 to 27. Claim 21 has also been amended to correct an obvious typographical error in the claim as previously submitted. In particular, claim 21 has been amended to read "... and expression of p21 is a relative expression of up to about 20,000 transcripts of p21...". Support for amended claim 21 can be found in the specification as originally filed, for example, at page 14, lines 9-11. Accordingly, these changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Introduction and Summary of Previous Proceedings***

A new non-final Office Action issued in the present application on March 7, 2007 (Paper No. 20070116). In this Office Action it was noted that the suspension of the present case has expired and the finality of the office action of 11/30/2005 has been withdrawn. *Id.* at p.2, first paragraph. It was also noted that the amendment of December 13, 2005 has been entered. However, the Examiner requested that Applicants submit a

new version of the claims because the previous submission is marred. *Id.* at p. 2, second paragraph. Applicants submit herein a new version of claim amendments.

The present Office Action also discusses previous interviews held in the present case on September 13, 2006 (summarized in Applicants' letter of October 4, 2006) and on January 4, 2007. *Id.* at p. 2, third paragraph. In particular, the present Office Action indicates that on January 4, 2007 the Examiner informed Applicants' representative that the "claims did not appear to [be] distinguishable over the putative prior art" and that a rejection under 35 U.S.C. § 102(e) would be made. *Id.* at p. 2, fourth paragraph. The Office Action also states that "much of what was submitted in the letter of October 4, 2006 seemed to be evidence and/or opinion and as such would have to be properly submitted in a rule 132 declaration." *Id.* Last, it was alleged "that the [previous] arguments failed to clearly make the case that [the] claimed cells were not anticipated by the cells disclosed in the '037 patent." *Id.*

The currently pending Office Action asserts rejections under 35 U.S.C. §§ 102 & 103. *See Id.* at pp. 3-9. Prior to filing a response in the present Office Action, Applicants' new representatives requested an interview with the Examiner. Applicants' new representatives thank the Examiner for granting this request. An interview with the Examiner was held on April 25, 2007. A summary of the interview is included below.

***Summary of the Interview Pursuant to 37 C.F.R. § 1.133(b).***

On Wednesday, April 25, 2007 an interview was held at the U.S. Patent Office between U.S. Patent Examiner Leon Lankford and representatives for Applicants, Jorge Goldstein (Reg. No. 29,021) and Doyle Siever (Reg. No. 47,088)) to discuss the currently pending rejection in U.S. Patent Application No. 09/960,244.

Representatives for the Applicants (hereinafter "AP-Rep") presented data provided by Applicants demonstrating the presence or absence of certain cell surface markers (*i.e.*, CD10, CD44, HLA-Class 1, and  $\beta$ -2 microglobulin) detected on Applicants' isolated cell populations (*i.e.*, adult bone marrow-derived somatic cells). The data presented during the interview is attached herewith as **Exhibit B**. AP-Rep pointed out to the Examiner that this

data clearly demonstrate that cells isolated by Applicants and those described in the patent issued to Furcht *et al* (*i.e.*, U.S. Pat. No. 7,015,037, hereinafter "the Furcht patent") are not the same cell populations, since the Furcht patent describes their bone marrow-derived cells as having the opposite expression profile with respect to these markers.

At this time, AP-Rep would like to clarify that the cells analyzed in **Exhibit B** were first isolated from a human donor in February 2004 using the methods described in the originally filed (and currently pending) patent application. AP-Rep would like to clarify this since AP-Rep believe that they might have stated during the interview that the cells analyzed in **Exhibit B** were isolated *prior* to the filing date of the present application. In fact, cell samples isolated prior to the filing date of the present application have also been analyzed for the same markers shown in **Exhibit B**, and these samples produced consistent results. However, cells taken from the February 2004 donor were used in evidence at the interview and are used herein because the 2004 cells have been more extensively characterized, especially through the higher numbers of population doublings as shown in **Exhibit B** and at the interview.

During the interview, AP-Rep also discussed possible claim amendments based on the observation described in the specification that the cell populations of the present invention consistently maintain low cell doubling rates over numerous population doublings. It was noted that a claim distinction based on this attribute alone is legally sufficient to distinguish the cell populations of the present invention from the cells claimed in the Furcht patent (regardless of the fact that both cell populations allegedly have cell surface markers CD49c and CD90 claimed in common).

AP-Rep also discussed the prejudicial and unfair use of the Declaration by Robert J. Deans against claims sought in Applicant's present patent application. AP-Rep pointed out that the method of isolating cells described in the Deans Declaration were not the same methods described in the Furcht '037 patent, but instead borrowed from the methods taught in *Applicants'* patent application. Hence, it was no surprise that the cells described in the Deans Declaration appeared to have a phenotype somewhat more similar to the cells described in the Applicants' patent application than those described in the Furcht patent.

AP-Rep also presented the Examiner with recent news articles in which serious questions have been raised, evidence has been presented, and admissions by the scientists have been made, which raise substantial concerns about the integrity and reliability of the data in the Furcht/Verfaillie '037 patent. The Examiner was apparently aware of these recent news articles. The Examiner recommended that AP-Rep submit copies of these news articles as part of an Information Disclosure Statement (IDS) in the present application. An IDS and copies of these publications are submitted herewith.

The Examiner concluded the Interview Summary report with the statement, "Applicants' evidence and arguments discussed in the interview would appear to overcome the rejection of record."

***Claim Rejections Under 35 U.S.C. §§ 102 and 103***

Claims 14, 19-21 & 24-25 have been rejected under 35 U.S.C. § 102(e) as allegedly "anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Furcht *et al* [U.S. Patent No. 7,015,037]." See, Paper No. 20070116, p. 4, second paragraph. In particular, the Office Action alleges the following points:

- "Furcht *et al* disclose a population of cell[s] which co-express CD49c and CD90 and is derived from human marrow."
- "Furcht suggests that the population can be pure or essentially pure and claims it as such."
- "Furcht is directly silent on doubling rate les[s] than about 30 hours but does disclose and claim a doubling rate of about 36 hours...[these] ranges are considered to overlap absent argument or evidence to the contrary."
- "As such...a holding of anticipation is required."

*Id.* at p. 4, last paragraph to p. 5, first paragraph. Further, it was alleged that "while Furcht is silent on some of the limitations of the dependent claims, as evidence suggests that the

cell populations are the same, those properties must be inherent to the cells and population disclosed by Furcht." *Id.* at p. 5, first paragraph.

The Office Action then addresses the topic of cell doubling rates. This issue will be discussed in further detail below and also in the Declaration Under 37 C.F.R. § 1.132 by Dr. Gene Kopen (attached herewith; the undersigned representative for the Applicants notes that, for convenience of review by the Examiner, an unexecuted *non-facsimile* copy of the Declaration is included along with the executed facsimile copy of the Declaration submitted herewith. Except for markings introduced as a result of facsimile transmission, the content of these documents is identical.). Before addressing the topic of cell doubling rates, however, it is first necessary to address the "Dean Declaration."

A substantial portion of the "evidence" mustered against the currently pending claims is derived from a Declaration by Robert J. Deans of Athersys Inc.<sup>FN1</sup> This Declaration (hereinafter the "Deans Declaration") was submitted during prosecution of the Furcht *et al.* patent application (serial no. 10/048,757) in attempt to provoke an interference with the present patent application. However, an interference was never declared. Instead, a patent with claims substantially copied from the present application was issued to Furcht *et al.* The allowance and issuance of these claims is based on the data and arguments found in the Deans Declaration.

As a threshold issue, Applicants strongly object to the use of this third party Declaration in the current *ex parte* proceedings. Use of the Deans Declaration in the *ex parte* prosecution of this application is highly prejudicial and improper because Applicants have had no opportunity to question or cross-examine the veracity or validity of the statements made therein by Robert J. Deans. If this was an interference proceeding,

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<sup>1</sup> For example:

- "Doubling rate is a product of the culture conditions as is discussed in the Dean Declaration in the Furcht patent application..." *See*, Paper No. 20070116, p. 5, second paragraph.
- "Further the Dean Declaration...sets forth data supporting the argument that the cells in '037 are the same as those instantly claimed..." *Id.* at p. 6, first paragraph.
- "In the Dean Declaration, the doubling rate...was calculated using Applicants' formula..." *Id.*

Applicants would have ample opportunity to cross examine Dr. Deans. But since this proceeding is purely *ex parte*, Applicants are severely prejudiced by the use of the Deans Declaration. Applicants therefore urge that the Examiner withdraw any rejections that are in any way based on the Deans Declaration as a matter of law.

In any event, and in view of the past and present prejudicial use of the Deans Declaration against Applicants' patent application, Applicants submit herewith a Declaration by Dr. Gene Kopen wherein many problems and errors inherent in the Deans Declaration are elucidated. Most importantly, however, the present Declaration by Dr. Gene Kopen and the data provided therewith demonstrate that the cells isolated in the Furcht patent are not the same cells as those isolated in the present application. Dr. Kopen is one of the co-inventors of the presently claimed invention and is a Senior Scientist at Neuronyx, Inc. (assignee of the presently claimed invention). Dr. Kopen has substantial experience and knowledge in the technological field of the presently claimed invention.

#### **Summary of Declaration by Dr. Gene Kopen**

The Declaration by Dr. Gene Kopen (hereinafter "the Kopen Declaration") presents fluorescence-activated cell-sorting (FACs) data demonstrating that the bone marrow-derived cell populations in the Furcht '037 patent have a different phenotype compared to the cell populations described and claimed in the present patent application.

In particular, the FACs data shows that Applicants' isolated cell populations are consistently negative for expression of cell-surface marker CD10 throughout numerous population doublings. In contrast, the isolated cell populations described in the Furcht patent are consistently described as positive for expression of CD10.

Conversely, the FACs data shows that the Applicant's isolated cell populations are consistently positive for expression of cell-surface markers CD44, HLA-Class I, and  $\beta$ 2-Microglobulin throughout numerous population doublings. In contrast, the isolated cell populations described in the Furcht patent are described as negative or variable in expression of these cell-surface markers, depending on the number of population doublings the cells have undergone.

The Kopen Declaration also reveals substantial and significant flaws, and thus, erroneous conclusions reached, in the Deans Declaration. In particular, the Kopen Declaration points out that the cells isolated in the Deans Declaration were not isolated using the procedures described in the Furcht patent. Instead, the isolation methods used in the Deans Declaration appear to be a mixture of the methods described in Applicants' present application combined with some of the procedures described in the Furcht patent. In particular, the cells isolated and assayed in the Deans Declaration were isolated without any immunoselection step (which is taught as being critical in the Furcht patent but which is not used in the present application) and cultured on fibronectin coated plates and in the presence of dexamethasone (a potent synthetic hormone) with supplemental PDGF-BB and EGF (which is taught as critical in Furcht, but not in Applicants' present application). *See*, Deans Declaration, p. 5 first sentence and p. 6, first full paragraph.

Hence, given this hybrid approach of Deans to the isolation of the cells assayed therein, it is not surprising that the cell populations described in the Deans Declaration might have some attributes in common with the cells described and claimed in the present application.

Most importantly, however, the Deans Declaration did not test the isolated cell populations described in the Furcht patent under the growth conditions described in Applicants' present application (as the Deans Declaration claims to have done).

The Kopen Declaration also points out that when the present application was filed it was well-known in the art that different types of cells require different subsets of growth factors. However, the cells described in the Furcht patent require supplemental growth factors (such as PDGF-BB and EGF) which are not required by the isolated cells of the present application.

The Kopen Declaration also discusses the usefulness of cell-doubling rates as a phenotypic measure of cell population homogeneity, especially the *constancy* of the cell doubling rate over many doublings. Using such measure, the Kopen Declaration points out that the *constant* population doubling rate phenotype of Applicants' isolated cells over many population doublings - in contrast to the ever-increasing population doubling rate observed for the Furcht cells - demonstrates that the isolated cell populations of the

present invention are not the same as the isolated cell populations claimed in the Furcht patent.<sup>FN2</sup>

Accordingly, the Kopen Declaration shows that those of ordinary skill in the art would *not* conclude, based on either the Furcht patent or the Deans Declaration, that the isolated cell populations in the Furcht patent are the same, or are substantially the same, as the isolated cell populations claimed in Applicant's present application.

### ***Doubling Rates***

The currently pending Office Action discusses cell doubling rates at page 5, first full paragraph through page 6, first paragraph. As an initial matter, the Office Action indicates: "It should also be noted that doubling rate is akin to an intended use of the claimed population as it is a measure of a process of use of the product, *i.e.*, the population." *Id.* at p. 5 first full paragraph. Applicants are confused as to the intended meaning and implication of this assertion. In particular, it is not clear to Applicants how a "doubling rate is akin to an intended use" of the claimed cell population. As indicated above, and as discussed at greater length in the Kopen Declaration filed herewith, the doubling rate of a cell population can be a useful phenotypic measure of the homogeneity of a cell population. Applicants are unclear, however, how a cell population doubling rate could be employed as a "process of use of the product." Should the Examiner believe this point warrants further discussion, Applicants respectfully request clarification of this issue.

The currently pending Office Action asserts that "The doubling rate of identical cells or populations would be an inherent property of the cells or population and as [such] *if the cells are the same* the doubling rates would necessarily be as well." *See*, Paper No. 20070116, p. 5, first full paragraph (emphasis added). Applicants agree with this statement. However, as discussed herein and in the Kopen Declaration, the presently claimed population of cells and the population of cells claimed in the Furcht patent *are not*

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<sup>2</sup> As noted by the Examiner, the ever-increasing cell doubling rate for the cells described in the Furcht patent was also exhibited by the cells isolated in the Deans Declaration. *See*, Paper No. 20070116, p. 6, first paragraph.

*the same.* Hence, even if they did exhibit the same population doubling rates, the cells would still be different.

In addition, the ever-changing doubling rates exhibited by the Furcht patent cell populations, compared to the *constant* population doubling rates maintained by the cell populations in the present application, provides additional phenotypic evidence that these two cell populations are not the same.

The Office Action also asserts:

Doubling rate is a product of the culture conditions as is discussed in the Dean[s] Declaration in the Furcht patent application and acknowledged in the instant specification... As such, *given that the cells of Furcht are isolated* from the same tissue, *in a like manner* to the isolation of the instant application, and [co-express] CD49c and CD90 the cells would appear to be the same and the doubling rate an inherent property.

*Id.* at p. 5, second paragraph (emphasis added).

Applicants respectfully disagree with this statement. In particular, although doubling rates *can be* a product of the culture conditions (*i.e.*, the doubling rate can sometimes be manipulated by the culture conditions), the doubling rate is not, and cannot, always be determined by the culture conditions. As discussed in the Kopen Declaration, all cells possess a maximum lower limit on how fast they can divide. And once cells, such as mammalian cells, begin to differentiate or otherwise enter G0, cell doubling stops, usually irreversibly so. Therefore, as cell population doubling times increase with each new generation, this increase marks changes taking place in the cell population such that the population cannot typically revert to doubling at its maximum lower limit (no matter how optimal the manipulation of culture conditions). Hence, doubling rate is not always a product of the culture conditions.

Further, the Office Action states "given that the cells of Furcht are isolated...in a like manner to the isolation of the instant application...the cells would appear to be the same..." *Id.* This assumption is incorrect because the cells of Furcht and of the present application are *not* isolated in the same manner. For example, and as discussed in the Kopen Declaration, the cells in Furcht are isolated using an immunoselection procedure,

followed by culturing on matrix coated surfaces<sup>FN3</sup> and supplementation with growth factors such as PDGF-BB and EGF. In contrast, none of these steps are utilized in isolating the cell populations of the present application. Hence, it is incorrect to say that "that the cells of Furcht are isolated...*in a like manner* to the isolation of the instant application" when, in fact, these two different disclosures use significantly different isolation procedures.

The present Office Action also states:

It should be further noted that since applicant's claims allow for up to about 9% of an unidentified cell type in their population, the doubling rate holds less meaning in that it does not serve to distinguish the cell population (or really the cells *per se*) from cells taught in the prior art. Applicant is claiming the cell doubling rate of an entire population of cells wherein a significant portion of the cells are not identified. The doubling rate could be greatly skewed by the presence of non-novel fast or slow doubling cells and as such it is hard to consider doubling rate a defining characteristic in the instant application.

*Id.* at p. 5, last paragraph to p. 6 first paragraph.

Applicants respectfully disagree with this assertion. As an initial matter, the term "greater than about 91%" has been deleted from newly amended claim 14 (and, therefore, also from the claims dependent thereon). With respect to the above quoted comments, however, it remains worth explaining that the isolated cell population is *claimed as a whole*, whether or not up to about 9% of the cells co-express or do not co-express CD49c and CD90. Thus, the doubling rate of "less than about 30 hours" applies to the cell population *as a whole* regardless of whether the cells are co-expressing CD49c and CD90. Therefore, the claim parameter "wherein the cell population has a doubling rate of less than about 30 hours" applies to the whole cell population, and serves to further distinguish the whole cell population from the prior art.

The Examiner also relies on the Deans Declaration to assert that the presently claimed cell populations are not distinguished over Furcht *et al.* because the cells isolated

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<sup>3</sup> *I.e.*, Negative immunoselection for CD45<sup>-</sup>/GlyA<sup>-</sup> cells or positive immunoselection for LIF receptor<sup>+</sup> cells and cultured on fibronectin coated surfaces. *See:* '037 patent, col. 7, lines 1-12; col. 15, lines 1-12; and, col. 44, line 51 to col. 45, line 35

in Deans were alleged to, at times, possess population doubling rates of about less than 30 hours. *See*, Paper No. 20070116, p. 6, last paragraph.

As already noted herein, and as discussed in the Kopen Declaration, the methods utilized in the Deans Declaration did not repeat the isolation procedures taught in the Furcht patent. Therefore, with all due respect, it is in error to hold out the cells in the Deans Declaration as being the same cells described in Furcht *et al.* Regardless, even if the cells isolated in Deans are comparable to those of the present application, the cells in Deans continue to exhibit cell doubling rates that slow down with increasing numbers of cell doublings, in contrast to the constant rates claimed in the present claims. This, in and of itself, should be considered a sufficient indicator that the cells in both the Furcht patent and in the Deans Declaration are not the same as those of the present application. Claim 14 (and thereby the claims dependent thereon) has been amended to recite "wherein the cell population *maintains* a doubling rate of less than about 30 hours *after 30 cell doublings*". This amendment serves to further distinguish the claimed cell populations of the present invention from the prior art. Accordingly, Applicants respectfully submit that the claims are properly distinguished over the prior art because only a single limitation, differing from the prior art, is necessary to show that the presently claimed invention as a whole is distinct from the prior art.

The present Office Action also discusses the previously pending claim parameter "wherein greater than about 91% of the cells" of the cell population co-express CD49c and CD90. In particular, relying on the experimentally flawed studies performed in the Deans Declaration, the Office Action discusses how this "91%" parameter is allegedly anticipated by the cells in the Furcht patent. *See*, Paper No. 20070116, p. 6 last paragraph through page 8. As already noted, claim 14 has been amended to delete the limitation "greater than about 91% of the cells." Accordingly, any issues with respect to percent "purity" of CD49c and CD90 co-expressing cells has been rendered moot.

Finally, the Office Action states "The Patent Office is not equipped to conduct experimentation in order to determine whether or not Applicants' [invention differs]...from that discussed in the references. ...the only way of overcoming such a clear holding of anticipation is factual proof that the rejection is in error." *See*, Paper No.

20070116, p. 9, first paragraph. As discussed above, the Declaration by Dr. Gene Kopen proves that the rejection is based on an incorrect assumption and that the presently claimed cell populations are not the same, nor are they substantially the same, as those described in Furcht *et al.*

In sum, Applicants have submitted in the Kopen Declaration plenty of evidence that the isolated cells of the present invention are not the same, nor are they substantially the same, as the cells isolated in Furcht *et al.* The evidence spans a number of phenotypic characteristics, including multiple markers, doubling rate constancy, and growth factor dependency. While this data taken as a whole demonstrates that the claimed cells are not the same as those of Furcht, it is only necessary *as a matter of law* to rely on one phenotypic difference, *e.g.*, the constancy of the doubling rate, to overcome the outstanding rejections. That is precisely what Applicant have done in this case.

In view of the amendments, explanations, data, and the Declaration under 37 C.F.R. § 1.132 submitted herein, Applicants respectfully request that all pending rejections be reconsidered and that the presently pending claims be allowed.

***Credibility of the Furcht Patent Has Been Questioned By The Scientific Community.***

Applicants wish to point out that the scientific community has raised serious questions with respect to the underlying data and validity of attributes alleged to be possessed by the "multipotent" bone marrow cells described in U.S. Patent No. 7,015,037 (the "Furcht patent"; currently licensed to Athersys Inc.). In February of 2007 several news articles publicly raised questions about data published by one of the co-inventors and lead investigators (Catherine Verfaillie) responsible for developing the bone marrow cells claimed in the Furcht patent. Upon request of the Examiner, copies of these publications are included herewith.

- NewScientist.com, "Flawed stem cell data withdrawn" (Feb. 15, 2007)  
[\(http://www.newscientist.com/article.ns?id=mg19325915.200\)](http://www.newscientist.com/article.ns?id=mg19325915.200)

- DeseretNews.com, "Study on uses for adult stem cells was flawed, panel says" (Feb. 25, 2007)  
(<http://www.deseretnews.com/dn/view/1,1249,660198505,00.html>)
- NYTimes.com, "Panel Finds Flawed Data in a Major Stem Cell Report" (Feb. 25, 2007)  
(<http://www.nytimes.com/2007/02/28/science/28stem.html?ex=1174708800&en=84aaf65fc6e7ec6e&ei=5070>)
- NewScientist.com, "Fresh questions on stem cell findings" (Mar. 22, 2007)  
(<http://www.newscientist.com/article.ns?id=mg19325964.600>).

In particular, it has been reported that a key paper published in *Nature* (vol. 418, p. 41 (2002)) by Catherine Verfaillie and others has now been acknowledged by Verfaillie to have flawed data that should not be relied upon. This paper was initially considered by the scientific community to represent a seminal breakthrough in adult stem cell research because the isolated bone marrow cells were reported to be capable of differentiating into a surprisingly vast number of cell types.

Even prior to Verfaillie's acknowledgment of unreliable data, the scientific community had begun to voice concerns about this publication because multiple laboratories were not able to reproduce Verfaillie's results (including scientists who worked in Verfaillie's own laboratory in attempt to reproduce the published results). *See*, publications cited above. In addition to questions concerning the reproducibility of Verfaillie's data, it has been reported that data in the key *Nature* publication was re-used in a subsequent publication (*Experimental Hematology*, vol. 30, p. 896 (2002)) even though, in the later use of this data, the data supposedly represented different cells, taken from different animals.

Most recently, NewScientist.com has reported finding misrepresentations of raw data published in the Furcht '037 patent and in a 2001 publication in the journal *Blood* (vol. 98, pp.2615-2625). *See*, NewScientist.com, "Fresh questions on stem cell findings" (Mar. 22, 2007) (<http://www.newscientist.com/article.ns?id=mg19325964.600>). In particular, it is reported that three images from the *Blood* publication are apparently duplicates of images

in the Furcht patent. However, in each case the images in the patent are used to describe the production of different proteins compared to those described in the Blood paper. In other words, the same data appears to have been "recycled" for use in describing different results in the Blood paper versus the Furcht patent. Stem cell biologists that were contacted independently by New Scientist are reported to be confident that the three images referred to above are duplicates. The problems with the data in the Blood paper are particularly significant in terms of planned clinical trials for these cells, because the Blood paper describes cells isolated from the bone marrow of human volunteers rather than experimental mice.

These recent critiques of what appear to be incorrect and irreproducible data in the Furcht '037 patent seem to be quite an eye opener to the scientific community. Applicants' have themselves observed – and point out in the Kopen Declaration - that the data in the Deans Declaration does not even reproduce the Furcht patent's own methods of isolating the stem cells (for example by leaving out a critical immunoselection step). Both of the scientific community's and Applicants' own observations therefore heighten the prejudice to Applicants in the use of Furcht et al and the Deans Declaration as credible evidence regarding the similarity (or lack thereof) of the Furcht/Verfaillie stem cells when compared to Applicants'.

### ***Conclusion***

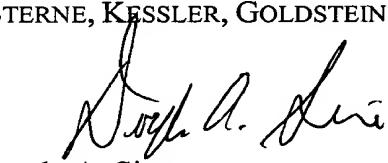
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will

expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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